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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------------|------------------|
| 10/057,414 | 01/25/2002 | John F. Shanley | 032304-040 | 9725 |
| 7590 06/21/2004 | | | | |
| CINDY A. LYNCH CONOR MEDSYSTEMS 1003 HAMILTON COURT MENLO PARK, CA 94025 | | | EXAMINER THALER, MICHAEL H | |
| | | | ART UNIT 3731 | PAPER NUMBER |

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,414

Applicant(s)

SHANLEY, JOHN F. *cn*

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-53,55,64-73 and 85-101 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-53,55,64-73 and 85-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 30, 2004 has been entered.

Claims 48-53, 55, 64-73, 85-101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 48, line 7, "having a hinge width" (singular) is confusing since the hinge is tapered and thus has many widths depending on where the width is measured. Thus, "the hinge width is smaller than the beam width" in line 8 is indefinite since it is unclear which hinge width (at the distal end, proximal end or at some other point along the length of the hinge) is referred to. Claim 85 is indefinite for the same reasons.

Claims 48-52, 55, 64, 65, 68, 73, 85-89, 91-93, 96 and 101 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fischell et al. (2004/0102836). Fischell et al., in figure 9, disclose

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beams 39, hinges 37, wherein the hinge width is smaller than the beam width (as seen in the figure), wherein the hinges each have a tapered portion such that an end of the hinge closer to an apex has a width which is greater than a width of the hinge at an opposite end (lines 9-11 of [0081] and lines 5-8 of [0068]), and the tapered portion has a length longer than a non-tapered portion of the hinge (The non-tapered portion of the hinge is located where hinge 37 merges with beam 39.). Alternatively, it would have been obvious that the hinge width is smaller than the beam width (at least slightly) since figure 9 shows this. As to claim 51, the Fischell et al. hinges inherently experience deformation below their elastic limit until the deformation is great enough to result in deformation above their elastic limit. As to claim 55, the Fischell et al. hinge width, length and taper are inherently adjusted (i.e. chosen, when it is manufactured) such that they inherently achieve a particular value of maximum strain along the hinge (which is chosen by the designer of the device). As to claim 68, the patentability of an apparatus does not depend upon it's method of manufacture. As to claim 73, Fischell et al. disclose a polymer in [0025] and [0089].

Claims 53 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (2004/0102836) in view

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of Drasler et al. (6,451,051). Fischell et al. fail to disclose a structure adjacent the hinges which experiences two degrees of freedom of motion during expansion. However, Drasler et al. teach that a stent should include a structure 250 adjacent the hinge (col. 45, lines 1-3) which experiences two degrees of freedom of motion during expansion (1, the pivoting of barb 250 from the position shown in figure 11B to the position shown in figure 11D wherein the pivot point is near node 365 and 2, the straightening of the barb along its entire length from the curved configuration shown in figure 11B to a straight configuration as shown in figure 11D as it pivots as indicated above). This arrangement has the advantage of better securing the stent in place in the body due to the barb. It would have been obvious to include such a barb on the Fischell et al. stent so that it too would have this advantage.

Claims 66, 67, 70, 71, 94, 95, 98 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (2004/0102836). As to claims 66, 67, 94 and 95, Fischell et al. fail to disclose teeth and a pawl. However, it is old and well known in this art to include disclose teeth and a pawl on a stent in order to insure that it remains expanded. It would have been obvious to include teeth and a pawl on the Fischell et al. stent so that it too would have this advantage. As to

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claims 70, 71, 98 and 99, Fischell et al. fail to disclose the amount of recoil claimed. However, it is old and well known in this art to construct stents with low recoil in order to insure that the blood vessel remains expanded. It would have been obvious to construct the Fischell et al. stent with low recoil so that it too would have this advantage. The above well known in the art statements are taken to be admitted prior art because applicant failed to traverse the examiner's assertions (M.P.E.P. 2144.03).

Claims 69, 72, 97 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (2004/0102836) in view of Harish et al. (6,506,437). As to claims 69 and 79, Fischell et al. fail to disclose apertures which receive the beneficial agent (the drugs described in [0025]). However, Harish et al. teach that a stent should include apertures to hold the beneficial agent disposed therein so that the beneficial agent can be reliably applied to the body. It would have been obvious to include apertures in the Fischell et al. stent so that it too would have this advantage. As to claims 72 and 100, Fischell et al. fail to disclose the biodegradable material. However, Harish et al. teach that part of the stent should be bioabsorbable in order to aid in delivering drugs to the body while preventing adverse local response (col. 5, lines

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18-49). It would have been obvious to include biodegradable material in the Fischell et al. stent so that it too would have this advantage.

Applicant's arguments filed March 30, 2004 have been fully considered but they are not persuasive for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
6/16/04



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731